



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,378	02/27/2002	Sean D. Monahan	13.04.05	8442

7590 07/13/2004
Mark K. Johnson
PO Box 510644
New Berlin, WI 53151-0644

EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,378

Applicant(s)

MONAHAN ET AL.

Examiner

James S. Ketter

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 2,3,16 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1636

The disclosure is objected to because of the following informalities:

At pages 15, 16 and 46 there are graphs which are not appropriate for the specification, and which should be therefore deleted from the specification and resubmitted as drawings, e.g., Figures 1-3. Also, upon so doing, Applicants should insert a BRIEF DESCRIPTION OF THE DRAWINGS section briefly describing these figures, being careful to avoid the introduction of new matter.

Appropriate correction is required.

Claims 2, 3, 16 and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitations of "mammalian vessel" in claims 2 and 16, and of "by increasing the permeability of the vessel" in claims 3 and 17 are redundant, those limitations already being present in the base claim.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

Art Unit: 1636

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 14-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11 and 5-8 of U.S. Patent No. 6,379,966 (A, newly cited), as follows: instant claims 1-3, 7-9, 14-17, 21 and 22 over patented claim 1, instant claim 10 over patented claim 5, instant claims 4 and 18 over patented claim 6, instant claims 5 and 19 over patented claim 7, and instant claims 6 and 20 over patented claim 8. Although the conflicting claims are not identical, they are not patentably distinct from each other because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). The MPEP states, at §804, that

[t]he specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Art Unit: 1636

The instant claim in each instance is more narrowly drawn than the patented claim.

However, the portion of US Patent 6,379,966 that supports each of claims 1-22 teaches each of the narrower limitations of the instant claims. Each of the instant claims is identical to the respective patent claim except that the recitation in each the instant claims of a particular cell type, i.e., extravascular muscle or liver cell, which would be encompassed by the term "parenchymal".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Simoes et al. (U, newly cited).

The instant claims are drawn to a complex comprising at least two compounds , which complex has a zeta potential which is not positive and which facilitates transfection of a nucleic acid into a cell.

Simoes et al. teaches, e.g., at Table 2, liposome-DNA complexes used to transfect cells, which complexes have, in a number of instances, negative zeta potentials. The complexes contain a mixture of DOTAP and DOPE lipids.

Art Unit: 1636

Claims 11-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Birchall et al. (V, newly cited).

The instant claims are drawn to a complex comprising at least two compounds , which complex has a zeta potential which is not positive and which facilitates transfection of a nucleic acid into a cell.

Birchall et al. teaches, e.g., in the Abstract, complexes for transfecting cells, which complexes are comprised of DDAB:DOPE and DNA, and which exhibit neutral, i.e., zero zeta potentials. Also, Figure 1B shows such complexes with zero and negative zeta potentials.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3 and 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 3, 16 and 17 are drawn to complexes. However, the claims from which they depend or ultimately depend, are drawn to a process, rendering the metes and bounds of the instant claims unclear. It would appear that the instant claims were meant to be drawn to the process. Furthermore, claim 3 depends from claim 4, which is a higher numbered claim. From context and comparison to claims 16 and 17, it would appear that it should depend from claim either claim 1 or claim 3.

Claims 18-20 are drawn to a process. However, claim 17 is drawn to a complex, itself unclear as being dependent from a process, as set forth above. As such, the metes and bounds of the instant claims are not clear.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.


Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

Art Unit: 1636

Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jsk
July 7, 2004



JAMES KETTER
PRIMARY EXAMINER